JAN 31 2000

510(k) SUMMARY

(As Required by 21 CFR 807.92)

Date Prepared: January 5, 2000

Submitter Name: BioSurgical Corporation
Contact:
Terry E. Laas
President
5990 Stoneridge Drive, Suite 112
Pleasanton, CA 94588
Phone: (925) 734-3009 Fax: (925) 737-1859

Device Name: Sealouette™ Fibrin Sealant Extended Droplet Applicator
Common/Usual/Classification Name: Piston Syringe
Devices to which Substantial Equivalence is Claimed: Sealouette™ Fibrin Sealant Applicator
Description of the Device:

The Sealouette™ Fibrin Sealant Applicator (predicate device) consists of a main housing, which holds a dual chamber syringe barrel and a common plunger that provides for the delivery and mixture of equal volumes of two-part fibrin sealant through a mixing chamber and application lumen.

The Sealouette™ Fibrin Sealant Extended Droplet Applicator (modified device) consists of the identical main housing, dual chamber syringe barrel, common plunger, and mixing chamber. The modified device has an extension, which places the application lumen farther from the applicator body. The extension does not affect mixing because the mixing occurs at the distal end of the tip in a geometry that is the same as in the predicate device.

The modified device has been shown to be substantially equivalent to the predicate device through a series of bench-top tests in which the properties of the fibrin sealant applied by both devices were shown to be equivalent. The tests included accuracy and reproducibility of fibrin sealant delivered, ability of the device to accurately and reproducibly deliver each component of the fibrin sealant in a fixed, one-to-one (1:1) ratio, the ability of the device to homogeneously mix the components of fibrin sealant, and the mechanical properties of the applied fibrin sealant.

Intended Use:

For the mixing, and one-to-one (1:1) delivery, of fibrin sealants for medical applications. It can also be attached to standard hospital wall suction for removal of debris, excess tissue or foreign particles in the wound.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2000

Mr. Terry E. Laas
President
BioSurgical Corporation
5990 Stoneridge Drive
Suite 112
Pleasanton, CA 94588

Re: K000048
Trade Name: BioSurgical Corporation Sealouette™ Fibrin Sealant Extended Droplet Applicator
Regulatory Class: II
Product Code: FMF
Dated: January 5, 2000
Received: January 7, 2000

Dear Mr. Laas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in

the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K000048

Device Name: Sealouette™ Fibrin Sealant Extended Droplet Applicator

Indications For Use

For the mixing, and one-to-one (1:1) delivery, of fibrin sealants for medical applications. It can also be attached to standard hospital wall suction for removal of debris, excess tissue or foreign particles in the wound.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use __

(Per 21 CFR 801.109)

Patricia Cucenta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000048